Lympha Press® 201Max™

Calibrated Gradient Pressure Compression Therapy System

User Manual

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Notes

Important - Before you Start

1. Please read this entire manual before using the system for the first time. Keep this manual handy for your reference.
2. Please record the contact information of your Lympha Press dealer (from whom you purchased the device). We suggest you write the dealer contact name, phone number and address on the inside page of this manual.
3. Please keep all packing materials in case you ever need to transport the pressure control unit. The packing materials have been specially designed to protect the system from damage during shipment.
4. You may register your product at www.lympha-press.com.

Indications

- Primary lymphedema
- Secondary lymphedema
- Venous insufficiency
- Venous stasis ulcers
- Dysfunction of the muscle pump

Contraindications

Use of the Lympha Press® 201Max™ system is not recommended in the presence of one or more of the following conditions:

- Known or suspected deep vein thrombosis or pulmonary embolism
- During the inflammatory phlebitis process
- Acute infection of the affected limb
- Decompensated cardiac failure
- Severe arteriosclerosis or other ischemic vascular disease
- Any circumstance where increased venous and lymphatic return is undesirable

Due to movement of fluids in the body when using the device, be careful with patients that have heart disease. Using high pressure is not recommended for patients having peripheral occlusion disease.

The abdominal area should not be treated during pregnancy. If an abdominal garment (Lympha Pants™, Lympha Jacket™, groin/abdomen garment or torso/abdomen garment) is to be used during pregnancy, the air cells over the abdomen must be disconnected prior to use.

Caution:

Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

Safety Warnings and Precautions

Warning: Explosion Hazard

Do not use Lympha Press® 201Max™ in the presence of flammable gases, including flammable anesthetics.

Warning: Electrical Shock Hazard

Do not allow liquid to enter any part of the Lympha Press® 201Max™ system. Do not immerse. To clean, follow instructions given in Sections 10.1 and 10.2 of this User Manual.

Warning: Electric Shock Hazard

To prevent electric shock, do not open the pressure control unit. Do not attempt to service the pressure control unit yourself. All maintenance tasks should be performed only by Lympha Press trained and authorized service personnel. Service by unauthorized personnel shall void any warranty.

Warning:

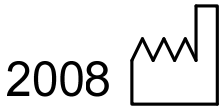
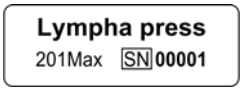
Hospital-grade electrical grounding is achieved only when connected to a hospital-grade receptacle.

Caution:

Use only cables and accessories approved by the manufacturer (Mego Afek AC Ltd.). Other cables and accessories may damage the system or interfere with system function.

Labels

The following labels and symbols appear on the pressure control unit, garments and/or packaging

Symbol	Description	Location
	Read instructions before use	On model number label. Located on base of pressure control unit
	Read instructions before use	On garment label
	Temperature limitations for storage and/or transport of the device	On pressure control unit carton
	Level of protection type BF equipment	On model number label. Located on base of pressure control unit
	Manufacturer's name and address	On garment label & on base of pressure control unit
	Date of Manufacture	On base of pressure control unit
	Serial number of the device	On back of pressure control unit
	CSA c/us Certification with respect to electric shock, fire and mechanical hazards only in accordance with CAN/CSA C22.2 No. 601.1-M90 (AM1+AM2) and UL 60601-1 (1st Edition)	On back of pressure control unit

1. Introduction - The Lympha Press® 201Max™ System

Lympha Press® 201Max™ is a calibrated gradient pneumatic compression therapy system for treatment of lymphedema, venous insufficiency, venous stasis ulcers and dysfunction of the "muscle pump".

The Lympha Press® 201Max™ system consists of:

- **The pressure control unit** (sometimes called "compressor" or "pump"), supplying air at fixed pressures to a compression garment that is worn over the area to be treated.
- **Hoses** that transfer the air from the pressure control unit to each of the cells in the compression garment.
- **The compression garment** (sometimes called a "sleeve"), fastened around the area to be treated. Each garment contains up to 24 overlapping air cells. These air cells are filled with air from the pressure control unit in sequence, applying a compressive massage. Once the entire limb has been compressed, Lympha Press® 201Max™ releases the pressure, and there is a brief pause. Then the process starts over again, and is repeated until the treatment session is complete.

The compress-and-release massage action of Lympha Press® 201Max™ stimulates lymphatic vessels in the treated area to take up and transport lymphatic fluid. The directional massage action encourages transport of the fluid towards the torso for collection by healthy lymphatics and return to the blood circulation. The directional compressive massage also helps reduce venous edema and stimulates venous return.

1.1. How it Works

Lympha Press® 201Max™ provides compression with short cycles of pneumatic pressure applied in short, steady cycles.

An air compressor in the unit distributes calibrated gradient pressure through a series of three individual regulators to the compression garment. The compression garment is fastened around the area to be treated.

The compression cycle is applied from distal (the hand or foot) to proximal (near or at the torso), applying pressure to the cells one after the other.

The pressure control unit allows setting pressure in three distinct zones along the garment. Pressure is adjusted as follows:

- Pressure regulator **DISTAL-1** provides pressure to cells 1 to 4 (zone #1).
- Pressure regulator **MEDIAL-2** provides pressure to cells 5 to 8 (zone #2).
- Pressure regulator **PROXIMAL-3** provides pressure to cells 9 to 12 (zone #3).

The inflation and emptying cycle is 26 seconds for inflation and four seconds for deflation and intermission. This short cycle time allows application of pressure to the treated area without discomfort.

The overlapping design of the air cells and the short duration of the treatment cycle enable smooth and efficient application of compression to the treated area.

Note:
Treatment pressure, time, and frequency must be prescribed by your physician.

1.2. The Massage Action

Lympha Press® 201Max™ applies directional massage that starts at the base of the treated area, starting over the foot or hand, and progressing upwards towards the torso.

This gradual, directional compression assists the flow of lymphatic fluid out of the swollen area and towards the lymphatic collectors in the torso. It prevents reflux ("wrong-way flow") of lymphatic fluid that could occur if only one discrete area was compressed each time. When the compression wave reaches the top of the limb, the pressure is released for a brief intermission, allowing for lymphatic and venous refill.

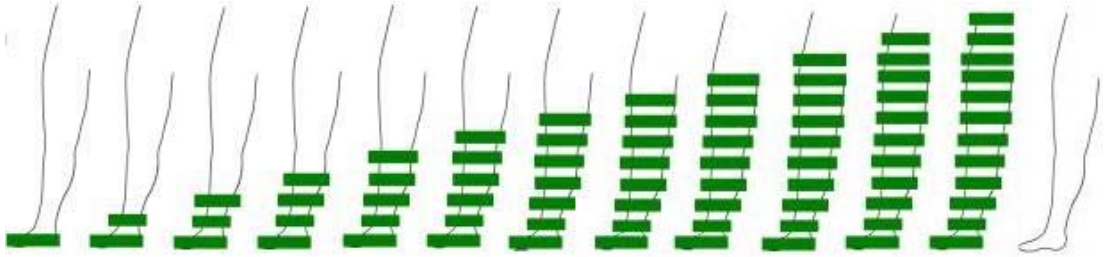


Figure 1 - The Compression Massage Cycle

1.3. Calibrated Gradient Pressure

- Lympha Press® 201Max™ has three zones of pressure. The pressure level can be set individually for each zone, according to physician prescription.
- **The pressure can be set at a gradient, if desired**, or can be set uniformly across the garment, with a slight drop in pressure between zones. The maximum pressure that can be set is 80 mmHg. The minimum therapeutic pressure that can be set is 20 mmHg. We do not recommend setting pressures lower than 20 mmHg. Pressure readings below 20 mmHg will not be displayed during operation.

Note:
The minimum pressure displayed during operation (**RUN** or **HOLD** modes) is 20 mmHg.

- Lympha Press® 201Max™ will not allow the setting of a higher pressure in a more proximal zone. This prevents inadvertent setting of a "reverse gradient" which could cause reflux or wrong-way flow.

Note:
The Lympha Press® 201Max™ pressure control unit will not allow setting a "reverse gradient". **This helps protect against reflux ("wrong-way flow")**.

1.4. Pressure Knob Lock

The Pressure Knobs have a tamper proof locking mechanism to prevent inadvertent change of pressure settings. To adjust the pressure, press and hold the Locking Button while turning the Pressure Knob (see Figure 2).

Figure 2 - Pressure Knob Lock

1.5. Treatment Garments

Lympha Press garments contain up to 24 air cells. Each air cell overlaps its neighbor for smooth directional compression massage, to gently direct the trapped lymphatic fluid to alternate pathways for uptake. Your physician will determine whether you need an extremity sleeve (arm or leg) or a torso garment (groin/abdomen, torso/abdomen, pants, or jacket).

2. Components of the Lympha Press® 201Max™ System

The Lympha Press® 201Max™ system consists of the pressure control unit, compression garment(s), and hoses.

2.1. Pressure Control Unit, Hoses, and Accessories

Table 1 - System Components

Component	Illustration
The **Pressure Control Unit** supplies air to the compression garments. There are two air outlets on the front of the unit. The **Hose Bundles** connect to these two outlets. The pressure control unit can operate two compression garments of up to 12 cells each (or one 24-cell garment) simultaneously.	
Power cord: the power cord is equipped with a hospital grade plug.	
The **Hose Bundle** transfers the compressed air from the pressure control unit to the compression garment. The type of hose bundle will vary according to the garment used.	

Component	Illustration
Plugs used to seal unused hoses or air outlets: • **12-prong Plug**: when using only one garment or hose, you must seal the second air outlet located on the front of the pressure control unit to keep air from escaping. Use this **12-prong Plug** to seal the unused outlet on the front of the pressure control unit. • **Double-sided Plug & Nozzle**: Unused hoses of active Hose Bundle must be capped off to keep air from escaping, using a **Nozzle** and **Double-sided Plug** (see Figure 3). A single **Double-sided Plug** can be used to seal off two hoses by utilizing its both sides (see Figure 3).	 **12-prong Plug** **Double-sided Plug** **Nozzle**

2.2. Optional Accessories

Table 2 - Optional Accessories

Component	Illustration
Remote Stop Used to stop the operation of the pressure control unit by hand without having to get up from the treatment position. Connect the remote stop to the Remote Stop Connector on the right side of the pressure control unit (see Table 4 - Remote Stop Connector).	

2.3. Compression Garments

Lympha Press® 201Max™ can be used with all our Lympha Press compression garments. Your Lympha Press dealer will select the appropriate garment for you, according to your physician instructions. Some garments have pressure limitations. If your physician recommends higher pressures, consult your Lympha Press dealer or call Lympha Press USA.

Caution:
Do not exceed the pressure limitations listed for your garment in Table 3 below. If your physician prescribes pressures higher than the limits for your garment, consult your Lympha Press dealer or call Lympha Press USA.

Table 3 - Lympha Press Garments

Garment	Area Treated	Pressure Limit	Figure
Zipper Sleeve	Arm or leg	• According to physician prescription • Can be used at full range of pressure	
Shoulder Attachment	Shoulder	• According to physician prescription • Can be used at full range of pressure	
FL Sleeve	Leg	• According to physician prescription • Can be used at full range of pressure	
Comfy Sleeve	Leg	• According to physician prescription • Can be used at full range of pressure	

Garment	Area Treated	Pressure Limit	Figure
Lympha Pants II™ Leg Sleeve	Leg (one or both), used with Lympha Pants II Groin/Abdomen Garment	• According to physician prescription • Can be used at full range of pressure • Abdomen - do not exceed 40 mmHg	
Lympha Pants II™ Groin/Abdomen Garment	Groin/abdomen (used with Lympha Pants II Leg Sleeve)	Do not exceed 40 mmHg over the abdomen	
Lympha Jacket II™ Arm Sleeve	Arm (one or both) used with Lympha Jacket II™ Torso/Abdomen Garment)	• According to physician prescription • Arm - can be used at full range of pressure • Abdomen - do not exceed 40 mmHg	
Lympha Jacket II™ Torso/Abdomen Garment	Torso, chest, back, shoulders, abdomen (used with Lympha Jacket II™ Arm Sleeve)	• According to physician prescription • Abdomen - do not exceed 40 mmHg	
ComfySleeve™ 1-75	Arm, torso, chest, back, shoulders, abdomen	• According to physician prescription • Arm - can be used at full range of pressure • Abdomen - do not exceed 40 mmHg	
Expander inserts	Used with all garments, to increase circumference. Shown: expander for Lympha Pants II.		

3. Setting up the System

Proper setup is essential for safe and comfortable treatment. Before using the Lympha Press® 201Max™ system for the first time, take care to arrange the treatment area so that the patient can reach the pressure control unit at any time during treatment.

Warning:
Use the Lympha Press® 201Max™ system only as prescribed by your physician.

3.1. Setting up the Pressure Control Unit

Place the pressure control unit on a flat stable surface from where it will not slip or fall, and locate it so that the patient can easily reach the controls during treatment. Do not place the pressure control unit on a tablecloth, fabric, cushion, or mattress, as this will block the air intake, which is at the base of the pressure control unit. Plug the pressure control unit into an appropriate 115-Volt wall outlet.

Note:
The air supply intake is at the base of the pressure control unit. Do not place the pressure control unit on a tablecloth, mattress, or other fabric surface, as this will block the air intake.

3.2. Attaching the Hoses to the Garment(s)

Note:
If you use the Lympha Pants II™, Lympha Jacket II™, or Comfy Sleeves, the hoses are already attached, so you can proceed to step 5.

1. Place the garment on a flat surface so that the sleeve air inlets face upward.
2. Note the numbers at the end of the hoses (see Figure 3). Each hose inflates one air cell.
3. Attach the hoses one by one to the air inlets, starting with hose #1 at the base (the hand or foot end) of the garment, securely into the air inlet.

4. Continue attaching the hoses to the air inlets in increasing numerical order, until all the air inlets have been fitted with a hose. **Hoses must be connected in the correct order, so that the air cells will inflate in the proper sequence.** Once properly connected, it is best to leave the individual hoses connected to the sleeve for future use.

> **Note:**
> Hoses must be connected in the correct numerical order, with hose #1 over the hand or foot, and the remaining hoses connected in increasing numerical order towards the torso, so that the air cells inflate in the proper sequence.

5. Disconnecting hoses: If you need to disconnect a hose from the air inlet, follow this procedure:
   a) Hold the air hose by its fitting.
   b) Hold down the air inlet with your other hand as you gently twist and pull the hose to work it free. Do not pull on the air inlet!
6. Extra hoses: If your garment has less than 12 cells, you will have one or more extra hoses. These unattached hoses must be sealed to prevent air leaks.
   a) Cap off the first hose in each zone with a Nozzle (see Figure 3), not a Double-sided Plug.
   b) Cap off all the remaining hoses using the Double-sided Plug (see Figure 3).

Hose Bundle

Two Hoses Capped by Double-sided Plug

Hose Capped by Nozzle

Figure 3 - Hose Bundle, Double-sided Plug, & Nozzle

3.3. Putting on an Isolating Garment

An isolating inner garment should be worn under all compression garments, for hygienic reasons. Stockinette can be worn under arm and leg sleeves, and is available from your Lympha Press dealer. For the Lympha Pants II™, you can wear light cotton tights or any light cotton unrestrictive pants such as sweats. For the Lympha Jacket II™, wear a comfortable, long-sleeved cotton T-shirt.

3.4. Putting on the Compression Garment

Your Lympha Press dealer will select a garment for you according to your measurements and physician prescription. The garment should fit snugly, but not too tight. **Find your garment on the list below and follow the instructions.**

3.4.1. Zipper Sleeves

These sleeves have three zippers for circumferential adjustment. Select the zipper that gives you a snug but not tight fit. If the sleeve is too small, an expander can be added to increase the circumference. As the treatment progresses the circumference of the limb changes. At that point, the sleeve can be adjusted by switching to another zipper to improve the fit.

a. First, attach all the hoses as described in Section 3.2 above. Be sure to cap any unused hoses. If you are using the optional shoulder attachment, zip it into place at the top of the sleeve and insert hose #11 into the air inlet on the shoulder attachment.

b. Close the zipper half way and insert the arm or leg (see the following note). Then zip the sleeve closed all the way. The shoulder attachment has a belt that you fasten around the back and chest. This helps support the sleeve and keeps it from sliding down.

Note:

Leg treatments with zipper sleeves may require the use of a separate boot.

3.4.2. Velcro Leg Sleeves

Velcro Leg sleeves are fastened with hook-and-loop fasteners.

a. First, attach all hoses, as described in Section 3.2 above, capping any unused hoses.

b. Insert the foot into the boot, pulling up on the sleeve to straighten it to its full length.

c. Close the fasteners snugly around the leg, starting from the foot. If the sleeve is too small, an expander can be added to increase the circumference. As the treatment progresses, the circumference of the limb changes and the fasteners can be closed to a smaller circumference.

3.4.3. Comfy Sleeves

These leg sleeves have the hoses pre-attached.

a. Open the zipper all the way.

b. Insert your foot into the boot, and then pull up on the sleeve to straighten it out to its full length.

c. Zip the sleeve closed. If the circumference is too small, an expander can be added.

3.4.4. Lympha Pants II™

Your Lympha Press dealer will assemble these modular pants for you, by attaching the groin/abdomen garment to one or two leg sleeves. Expanders may be added as necessary to increase the circumference.

Treatment with Lympha Pants II™ is always performed with the patient lying down.

- **Do not use the pants in a recliner or a chair.**
- **The patient must have the hips in line with the legs. This is to prevent formation of folds in the garment that can block the air flow. Keeping the hips in line with the legs also helps promote lymphatic and venous return. Pillows can be used to prop up the patient's back and shoulders as needed for comfort.**
- Set up the pressure control unit prior to getting into the pants, and locate the unit so that you can reach the device controls easily during treatment.

Putting on the pants:

a. First connect the hoses to the two air outlets at the front of the pressure control unit, making sure they snap into place.

b. Lay the pants on the treatment area (bed or sofa), and open up the white zipper on each side up to mid-leg. (One-legged pants have only one white zipper; you can also open up the zipper on the short side), unbuckle the abdominal flaps and spread them out.

c. Get into the pants from a sitting/lying position, until you are all the way inside.

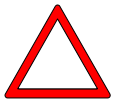
d. Fold the abdominal section over your belly and fasten the buckles for a slightly loose fit. Slender patients may find that this section overlaps considerably.

e. Zip up the zippers to the top.

f. Place a cushion under the leg sleeve where your foot ends, to slightly elevate the sleeve in the shape of a boot. You may need assistance to do this the first time, until you decide on a comfortable position for pillows, etc.

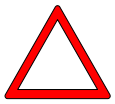
g. Before turning on the pressure device, lightly flex the feet so that they will be in a comfortable position as the pants are filled with air.

h. If the weight of the hose bundle pulls down on the feet, support the hose bundle by hanging it over a chair or the bed rail, or by placing a pillow under the hose bundle where it exits the pants.



Caution:

Using pressure over 40 mmHg on the abdominal area is not recommended.



Caution:

The abdominal area should not be treated during pregnancy. If Lympha Pants II™ is to be used during pregnancy, the air cells over the abdomen must be disconnected and plugged prior to use.

3.4.5. Lympha Jacket™ & Lympha Jacket II™

Your Lympha Press dealer will assemble a modular garment for you, by attaching the torso/abdomen garment to one or two arm sleeves. The Lympha Jacket II™ can also be supplied as a single unit. Expanders may be added as necessary to increase the circumference.

Lympha Jacket II is a unique treatment system for the entire upper body. When used to treat both arms, it will inhibit your mobility, so please follow these instructions.

a. Set up the pressure control unit where you can reach it easily from the treatment position. Be sure you are sitting within easy reach of the pressure unit controls.

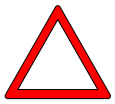
b. Open the jacket at the front zipper and put it on.

c. If you are treating both arms, open up one arm zipper to just above the wrist to free one hand to operate the pressure control unit.

Warning:

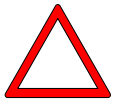
If you cannot operate the pressure control unit, you will need to have someone with you during treatment, to help you turn Off the unit if necessary.

d. Close the front zipper. Adjust the front fasteners for a comfortably snug fit across your chest and abdomen. If the jacket is too small, additional expanders can be added at the arm or at the back zipper.



Caution:

Using pressure over 40 mmHg on the abdominal area with the Lympha Jacket™ or Lympha Jacket II™ is not recommended.



Caution:

The abdominal area should not be treated during pregnancy. If Lympha Jacket™ or Lympha Jacket II™ is to be used during pregnancy, the air cells over the abdomen must be disconnected and plugged prior to use.

3.4.6. ComfySleeve™ 1-75

a. ComfySleeve 1-75 can be used lying down, or in a seated position with the treated arm comfortably elevated on a chair arm or sofa back. During treatment the arm should be positioned at approximately 90 degrees (straight out) from the torso. This will enable full contact of the garment with the armpit and shoulder during treatment.

b. Make sure the pressure control unit is located where you can reach it easily during treatment.

c. Attach the hose to either air outlet of the pressure control unit and cap the other air outlet with the gray 12-prong Plug, provided.

Note:
ComfySleeve 1-75 is a modular garment consisting of torso sleeve, arm sleeve, and side fastener which are all zipped together. Follow the steps below for putting on and removing the assembled garment.

d. Lay the garment on a flat surface. With the front of the garment facing you, locate the zipper of the side fastener which will be toward the front when you put on the garment. The front and back of the garment look very similar, so orient yourself according to the arm sleeve.

e. Open up the zipper of the side fastener toward the front. (DO NOT open the zipper towards the back of the garment).

f. Open the zipper at the wrist of the arm sleeve. This will allow you to use both hands to fasten the garment once you have put it on.

g. Loosen the side straps to nearly their full length. This will enable you to grasp them once you have put on the garment.

h. Put on the garment, as you would a jacket.

i. Pull the inner padded section of the side fastener (attached to the side straps) around your torso and lightly fasten the Velcro at the top and bottom, so that the garment is closed around you. This allows you to let go of the garment and grasp the zippers.

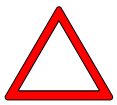
j. Find the zipper of the side fastener, and zip the garment closed at the front.

k. Tighten the fasteners at the side for a comfortable fit. It does not need to be tight; in fact you may feel the massage better on your torso if it is not too snugly fastened. If during treatment the compression feels uncomfortable, you may slightly release any of the fasteners at the side to loosen the fit.

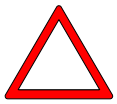
l. Insert the connectors on the sleeve to the connectors on the hose (gray to gray and white to white). You can also do this before you put on the garment, if it is easier for you to do so at that time.

m. Zip the wrist zipper closed.

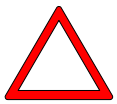
n. Follow the directions for operating the pump.



Caution:
Stop treatment and consult your medical practitioner if there is onset of pain, bruising or irritation during or after treatment.



Caution:
Using pressure over 40 mmHg on the abdominal area with the ComfySleeve™ 1-75 is not recommended.



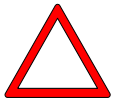
Caution:
The abdominal area should not be treated during pregnancy. If ComfySleeve™ 1-75 is to be used during pregnancy, the air cells over the abdomen must be disconnected and plugged prior to use.

3.5. Attaching the Hose Bundle to the Pressure Control Unit

1. Locate the big gray hose connector at the other end of the hose bundle. All twelve hoses join at this gray connector. Note the snap tooth on the top of the hose connector. Also note the two air outlets on the front of the pressure control unit. You can insert the air hose into either outlet.
2. Insert the hose connector into one of the two air outlets at the front of the pressure control unit, making sure the snap tooth is facing UP. The hose connector will "click" into place. If you do not hear a click, move it gently to make sure it is secure.
   a) To remove the hose connector, press down on the snap release and pull out the connector.
   b) If you are treating only one limb, plug the unused air outlet at the front of the pressure control unit with the 12-prong Plug (you will find this in the zipper accessory bag supplied with the pressure device). It is important to plug this outlet. If it is left open, air will escape and the pressure control unit will not function.

Note:

When only one air outlet is in use, insert the 12-prong Plug to seal the second, unused air outlet. If you do not plug this outlet, the pressure control unit will not operate efficiently and may not inflate the garment properly.



Caution:

If immediate garment deflation is necessary, disconnect the hose bundle from the pressure control unit to immediately deflate the air pressure in the garment.

4. Operating Lympha Press® 201Max™

Following is a description of the pressure control unit operating panel and the various settings and displays (see Figure 4). Please read this section before operating the pressure control unit for the first time.

Figure 4 - The Pressure Control Unit Operating Panel

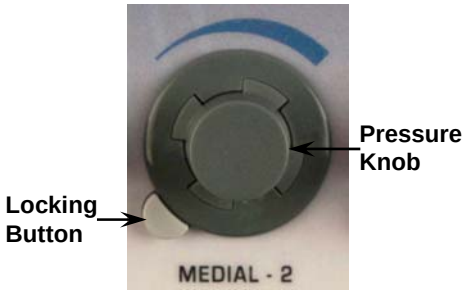
4.1. Initial Display

When Lympha Press® 201Max™ is switched On, the display screen shows **READY Press Start** (see Figure 5).

Figure 5 - Initial Display

4.2. The Device Controls

Table 4 - Device Controls

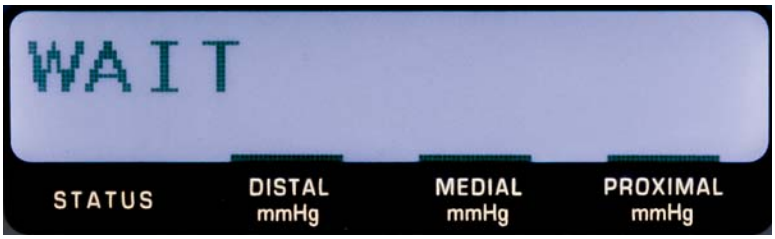
Control	Function
	**Pressure Knob**: Three rotatable pressure regulators each equipped with a Locking Button. **Locking Button**: • **Normally Released**: Disables rotating the Pressure Knob to prevent unintentional change of pressure settings. • **Press and Hold**: Enables rotating the Pressure Knob (see Section 1.4, Figure 2).
	START/STOP Button: Press this button to start or stop treatment.
	Main Switch: Turn the switch to **I** to turn On the unit or to **O** to turn Off the unit.
	• **USB Connector**: For service use only. • **Remote Stop Connector**: used to connect the optional remote stop accessory.

5. Setting the Pressure

5.1. Pressure Gradient Setup

The following procedure describes how to set up the pressure gradient of Lympha Press® 201Max™ according to physician prescription.

1. Press and hold the **START/STOP** button.
2. Turn **On** the device while pressing the **START/STOP** button.
3. Release the **START/STOP** button only after the following display appears:



4. Wait until the following display appears (within 30 seconds):

5. Adjust the pressure gradient according to physician prescription, starting from distal (Pressure Knob **DISTAL-1**) to proximal (Pressure Knob **PROXIMAL-3**).
   - The minimum therapeutic pressure that can be set is 20 mmHg. We do not recommend setting pressures lower than 20 mmHg. Pressure readings below 20 mmHg will not be displayed during operation.
   - The maximum pressure that can be set is 80 mmHg.

> **Note:**
> The minimum pressure displayed during operation (**RUN** or **HOLD** modes) is 20 mmHg.

6. To exit the **Setup** mode, press the **START/STOP** button.

   The following display appears:

Lympha Press® 201Max™ is now ready for operation.

Note:

Lympha Press® 201Max™ does not allow setting a reverse gradient.

- You can decrease the pressure of zone #1 until it reaches the pressure of zone #2.
- If you continue reducing the pressure of zone #1, then the pressure of zone #2 will also be reduced until it reaches the pressure of zone #3.
- If you continue reducing the pressure of zone #1, then the pressure of zone #2 and zone #3 will be reduced as well.

5.2. Fine-tuning Pressure While the Unit is in Operation

To adjust pressure while the pump is in operation:

1. Wait until three inflation cycles have been completed. During the fourth inflation cycle, when all cells in the required zone have been fully inflated, proceed to Step 2.
2. Press and hold the Locking Button.
3. Slightly rotate the Pressure Knob while pressing the Locking Button, until the required pressure is displayed.
4. Release the Locking Button.
5. Repeat steps 2 to 4 for the remaining zones, until reaching the required pressures.
6. You may need to repeat these steps as the device is cycling during the procedure.

6. Preparing for Treatment

Now you are ready to operate the pressure control unit and begin your treatment.

1. Ensure that all tubes are properly connected to the garment and that the hose bundle is securely attached to the pressure control unit.
2. Verify that the Main Switch at the back of the pressure control unit is in the **OFF** position.
3. Connect the power cord to the pressure control unit and then connect the power cord to the electrical outlet.

Note:

Before connecting the pressure control unit to the electrical outlet, make sure that the power supply is 115 Volts and verify that the electrical outlet is grounded.

4. Turn On the Main Switch, located at the back of the pressure control unit.
5. Get into a comfortable seated, reclining, or lying position from where you can easily reach the pressure device controls. Put on the garment, following the directions in Section 3.4 above.

7. Starting the Treatment

Note:

Lympha Press® 201Max™ is set to operate for 60 minutes. If not turned Off manually, the unit will automatically stop after one hour. The 60-minute timer will be reset every time the unit is turned OFF or START/STOP is pressed. If longer treatment sessions are required, you may deactivate the timer by using the HOLD mode (see Chapter 9, below).

1. Press the **START/STOP** button to begin treatment. The treatment proceeds according to the pressure settings.
   - □ During treatment, the display shows the pressure progress zone by zone (see Figure 6).
   - □ The pressure is displayed both numerically and visually by a progress bar (see Figure 6).
   - □ In addition, **RUN** is displayed on the left side with a rotating icon above (see Figure 6).

Figure 6 - Treatment Display

2. If you wish to change the pressure while treatment is in progress, you can change the pressure for each zone separately using the instructions for Fine-tuning the pressure (see Section 5.2 above).

Note:

At the start of treatment, the garment may take several inflation cycles to fill completely, as the garment must be filled from a completely empty state.

8. Ending the Treatment Session

1. When you wish to end the treatment session, press **START/STOP**. If the **START/STOP** button is not pressed, the treatment timer will end the session automatically after 60 minutes.
2. When treatment stops, wait up to 30 seconds to allow the garment to deflate before you remove it.

9. Using the HOLD Mode (Treatment Timer Deactivated)

If your physician has prescribed a treatment time longer than 60 minutes, use the **HOLD** mode. This allows treatment to run continuously until the **START/STOP** button is pressed.

1. To access **HOLD** mode, press and hold the **START/STOP** button for around five seconds, until the unit starts operating.
2. During operation in **HOLD** mode, **HLD** is displayed instead of **RUN**. This will inform you that the timer is deactivated.

Figure 7 - HOLD Mode Display

3. To end treatment while in **HOLD** mode, press the **START/STOP** button.
4. Wait up to 30 seconds to allow the garment to deflate.
5. When the garment has deflated, remove the garment and turn Off the Main Switch.
6. Ending the treatment or powering Off the system returns the system to regular timed operation mode.

Warning:
In **HOLD** mode, treatment will run indefinitely unless stopped by pressing the **START/STOP** button.

Note:

- To operate the system with the 60-minute timer, **press and release** the **START/STOP** button. The screen will display **RUN**.
- To operate the system continuously, without the timer, **press and hold** the **START/STOP** button for around five seconds. The screen will display **HLD**.
- Pressing **START/STOP** or powering Off the system will reset the timer to 60 minutes.

Caution:

In case of power failure, or when immediate garment deflation is necessary, disconnect the hose bundle from the pressure control unit to immediately deflate the air pressure in the garment.

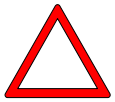
10. Maintenance & Storage

10.1. Cleaning the Pressure Control Unit

1. Ensure the electrical cord is unplugged before cleaning the pressure control unit.
2. Wipe clean using a **slightly damp cloth**.
3. Do not allow any moisture or liquids to enter the device!

10.2. Cleaning the Compression Garment

1. Gently wipe the compression garment using a damp soft cloth, moistened with a mild detergent solution.
   - Do not use hot water - the temperature should always be under 100°F.
   - Do not allow any liquid to get into the air inlets.
2. After cleaning, thoroughly wipe the compression garment dry using a soft towel only.
   - The compression garment may be surface wiped with a light application of appropriate hospital grade disinfectant such as 50% alcohol.
   - Do not use bleach! Allow to air dry completely before using the garment.



Caution:

- Do not hand or machine wash. Surface wipe only!
- Do not allow liquid to get into the air inlets.
- Do not use bleach.
- Do not dry clean.
- Do not wring, iron, tumble or force heat dry.

10.3. Storage and Transportation

- □ Keep the pressure control unit, hoses and garments away from direct sunlight.
- □ Store in a dry, shaded place (see Caution below).
- □ Do not twist or fold the hose bundle.
- □ Store the electric cord lightly wrapped and secured.

Caution:

The system can be transported or stored for short periods of time within temperature ranges of -40°F to 158°F (-40°C to 70°C), relative humidity of 10% to 93% non-condensing, and atmospheric pressure of 190hPa to 1060hPa.

Allow the system to reach reasonable room temperature 50°F to 86°F (10°C to 30°C) before operating.

11. Troubleshooting

Table 5 - Troubleshooting

Problem	Display Indication	Cause	How to fix the problem
Device operates, but the garment does not fill with air to required pressure.	No pressure displays on LCD	External air leakage	• Verify that hose bundle connector is securely connected to the pressure control unit. • Verify that all hoses in use are securely inserted into the garment. • Verify that all unused hoses are securely capped (see Section 3.2 - Step 6). • If using only one garment, verify that the unused air outlet is securely plugged with the 12-prong Plug.
		Internal air leakage	Contact Lympha Press USA for service.
Main Switch is not illuminated when switch is turned to **ON** position. Pressure control unit does not turn On.		No electric supply	• Make sure device is plugged into the appropriate wall outlet. • Verify that the power cord is securely inserted in its socket at the back of the device.
		Internal electric malfunction	Contact Lympha Press USA for service.
Main Switch illuminated, but the display does not appear on screen.		Internal electric malfunction	Contact Lympha Press USA for service.
Loud/abnormal noise.		Internal mechanical vibration	Contact Lympha Press USA for service.

11.1. Repairs and Technical Support

Contact your Lympha Press dealer, or call us at Lympha Press USA.

11.2. How to Contact Us

Lympha Press USA

232 Park Avenue

Manalapan, New Jersey 07726

Toll-Free: 888-LYMPHA-1

Tel: 732-792-9677

Fax: 732-792-9745

Web: www.lympha-press.com

Email: info@lympha-press.com

11.3. Manufacturer

Mego Afek AC Ltd. Kibbutz Afek 30042 Israel

11.4. Manufacturer Warranty

Mego Afek AC Ltd. warrants the Lympha Press® 201Max™ Compression Therapy pressure control unit and Lympha Press compression garments to be free of defects in materials and workmanship for a 12-month period from the date of purchase. During this period, if properly handled and maintained, a defective pressure control unit, hoses and/or garment(s) shall be repaired free of charge.

Warranty does not cover malfunctions caused by misuse, noncompliance with usage guidelines and/or maintenance instructions, or damage caused by repair work performed by unauthorized personnel.

Appendix - Specifications

Sequential Therapy Device Model: 201Max®, appliance coupler, transportable, rated: 115 VAC, 60 Hz, 1.5 A	
Type of protection against electric shock	Class I
Degree of protection against electric shock	Type BF
Degree of protection against ingress of water	IPX0
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Mode of operation	Continuous
Environmental Conditions	Normal: 10-30°C, 30-75% rH, 700-1060 hPa
Pressure Range	20 mmHg to 80 mmHg
Size	15 cm × 32 cm × 38.5 cm (6" × 12½" × 15¼")
Weight	5.3 kg (11.7 pounds)